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SENATE JOINT RESOLUTION 49
By McNally

A RESOLUTION to request the Food and Drug Administration and the Tennessee State Board of Pharmacy in consultation with the Licensed Medical Practitioners of Tennessee and input from the TennCare Pharmacy Committee to take additional measures to protect the safety and health of patients being treated with medications identified as Narrow Therapeutic Index (NTI) Drugs.

WHEREAS, The health and safety of millions of Americans suffering from a variety of potentially debilitating and sometimes life-threatening diseases depend upon treatment with a special class of medications identified by the Food and Drug Administration as Narrow Therapeutic Index (NTI) Drugs; and

WHEREAS, Narrow Therapeutic Index Drugs must be prescribed, used and monitored with great care as even a slight change in dosage may result in either ineffective therapy or produce toxic effects, potentially jeopardizing patient safety; and

WHEREAS, Patient safety depends to a large extent on increased awareness on the part of the public and public policy-makers that NTI medications warrant special consideration; and

WHEREAS, It is important to communicate to all who make decisions about the availability of NTI medications that substitution of formulations of NTI drugs should never be mandatory, and any substitution or interchange of formulations should take place only with the express knowledge and consent of the patient and the treating physicians; now, therefore,

BE IT RESOLVED BY THE SENATE OF THE ONE-HUNDREDTH GENERAL ASSEMBLY OF THE STATE OF TENNESSEE, THE HOUSE OF REPRESENTATIVES CONCURRING, That the U.S. Food and Drug Administration be encouraged to establish individual bioequivalency and therapeutic standards for generic formulations of NTI medications to reduce the risk of product variability; and

BE IT FURTHER RESOLVED, That the Tennessee Board of Pharmacy, in consultation with the Licensed Medical Practitioners of Tennessee and input from the TennCare Pharmacy Committee, and the University of Tennessee, Memphis, the Health Science Center, are encouraged to take additional steps specifically designed to further protect patient health and safety by establishing through regulations strict standards regarding the substitution and interchange of NTI Drugs, including that they may not be substituted without the express knowledge and consent of both the patient and the treating physician.

BE IT FURTHER RESOLVED, That appropriate copies of this resolution be forwarded to the Commissioner of the Food and Drug Administration and Tennessee Board of Pharmacy.

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